510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

A. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
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Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs - Devices Renal Therapies Group
Date of Preparation:	25 June 2013

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B. Device Name

Trade Name:	2008T Hemodialysis Machine
Common Name:	Hemodialysis Delivery System
Classification Name:	High Permeability Hemodialysis System
Classification Number:	Class II per 21 CFR § 876.5860
Product Code/Classification Panel:	78 KDI, KPO; Gastroenterology/Urology Panel

C. Legally Marketed Predicate Devices

2008T Hemodialysis Machine (K121341) and Crit-Line Clip Monitor (K121599).

D. Device Description

The 2008T Hemodialysis Machine is indicated for acute and chronic dialysis therapy. In the extracorporeal blood circuit, blood is continuously circulated from the patient through a dialyzer, where toxins are filtered out through a semi-permeable membrane, and returned to the patient. During this process, the extracorporeal blood circuit is monitored for venous and arterial blood pressures, and for the presence of air and blood. In the dialysate circuit, the dialysate concentrates are mixed with purified water, heated, degassed, and delivered to the dialyzer. Balancing chambers ensure that the incoming flow of the dialysate is volumetrically equal to the outgoing flow in order to control ultrafiltration from the patient.

The display screen of the 2008T Hemodialysis Machine is shared between the hemodialysis machine and the CDX PC (optional) running third party MDDS (Medical Device Data Systems). The blue CDX Key located on the fold-down keyboard allows switching between the Dialysis Screen and the MDDS screen. The user interface of the 2008T Hemodialysis Machine which includes a keyboard, touchpad and touch-screen, is operational in both the dialysis mode and the CDX mode, whichever is actively displayed.

Bibag System (Optional):

The bibag system is intended for use with Fresenius three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

The 2008T Hemodialysis Machine with bibag System allows operators the option of preparing a saturated sodium bicarbonate solution online through automated mixing of dialysis grade water and dry sodium bicarbonate powder within the bibag source disposable. The bibag System comprises: (1) the sodium bicarbonate concentrate generator (known as the bibag module); and (2) the bag of dry sodium bicarbonate concentrate. A specialized bibag connector with a door is used to connect the single-use bibag disposable (650g/900g) filled with USP grade dry sodium bicarbonate powder to the bibag connector. The 2008T Hemodialysis Machine draws dialysis grade water into the bibag to produce a saturated solution of sodium bicarbonate online. This online generation of sodium bicarbonate can only be performed using a specially modified 2008T Hemodialysis Machine with bibag System and can only be used with 45x (1:44) dilution.

Modifications to the previously cleared 2008T Hemodialysis Machine (K121341) include:

- **Crit-Line Clip Monitor (CLiC) (Optional):** Hardware, software and labeling modifications to integrate the Crit-Line Clip Monitor (CLiC; K121599) and expansion of the Indications for Use for use of the CLiC with the 2008T Hemodialysis Machine. When integrated with the 2008T Hemodialysis Machine, the CLiC will use the same technology cleared under K121599, except the CLiC will now be hosted by the 2008T Hemodialysis Machine instead of the medical grade computer. When installed, the Crit-Line monitoring feature/user interface will be optional, selectable in Service Mode.

  The intended use of the CLiC is as a continuous real-time monitor for non-invasive hematocrit, oxygen saturation, and percent change in blood volume measurement during hemodialysis treatment. The CLiC uses the principle of light absorption and scattering through the blood under test to measure oxygen saturation (O_2 Sat) and hematocrit (Hct). The Hct values are then used to calculate the Blood Volume (BV) percentage change relative to the starting BV based on the beginning Hct.

- **Software Maintenance:** Software maintenance modifications were made to the 2008T Hemodialysis Machine since the last clearance (K121341).

- **Additional Labeling Modifications:** The 2008T Hemodialysis Machine Operator's Manual contains modifications to warnings concerning Total Buffer which were implemented as part of a Class I recall for Naturalyte/Granuflo Prescribing Information (Recall number Z-1826/Z-1827-2012).

  The device description information included in the submission conforms to the applicable requirements of 21 CFR Section 876.5860(b).

E. Indications for Use

2008T Hemodialysis Machine:

The 2008T Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

bibag System (Optional):

The bibag system is used with Fresenius Medical Care three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

Crit-Line Clip Monitor (CLiC) (Optional):

The Crit-Line Clip Monitor is used with the 2008T Hemodialysis Machine to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC device measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e. increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting.

F. Intended use

The intended use of the modified 2008T Hemodialysis Machine with optional bibag is the same as the unmodified device (K121341). Both devices are intended to be used for acute and chronic dialysis therapy in patients with End Stage Renal Disease.

The intended use of the Crit-Line Clip Monitor when installed and used with the 2008T Hemodialysis Machine is the same as the predicate device (K121599). The CLiC is intended to be used as a non-invasive hematocrit, oxygen saturation and percent change in blood volume monitor during hemodialysis treatment.

G. Technological Characteristics

The technological characteristics of the proposed device are summarized in the context of the predicate devices:

2008T Hemodialysis Machine with optional bibag System (K121341)

The modified device has the same operating principle, fundamental scientific technology, and is comparable in key safety, effectiveness and quality assurance features.

All existing water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines, and language options remain unchanged from the predicate device.

The following technical specifications of the modified device remain the same as the predicate device:

- Safety system
- System performance
- Environmental Requirements
- User Interface (except for CLiC features)
- Hardware and therapy settings
- Accessories (except for CLiC sensor clip)
- Alarms (except for additional alerts/warnings associated with the CLiC)
- Accuracy and Controls
- Protection against Mechanical Hazard
- Protection against Electrical Hazard
- Protection against excessive temperature or other hazards
- Transportation and Storage conditions
- Manufacturing Location and manufacturing processes (assembly, fabrication, testing, shipping, installation and service).

Crit-Line Clip Monitor (CLiC):
The Crit-Line Clip Monitor (CLiC) proposed for use with the 2008T Hemodialysis Machine is the same device cleared for use with the medical grade computer during hemodialysis treatments under K121599.
The CLiC has the following key similarities to the predicate device (K121599):

- Intended Use
- Operating Principle
- Fundamental Scientific Technology
- Performance Specifications (monitoring parameters)

Safety and effectiveness of the 2008T Hemodialysis Machine with optional CLiC is confirmed by system verification and validation testing to verify performance specifications, and user requirements, in conformance with applicable referenced FDA regulations and FDA-recognized industry and international standards.

A risk analysis (per ISO 14971) has been completed and potential hazards associated with the modifications are identified and mitigated. Mitigations are verified wherever applicable. All potential risks were deemed acceptable after mitigation.

H. Performance Data

The performance of the modified device described in this submission was evaluated according to existing FMC-RTG procedures, protocols, declared performance standards and guidelines of the quality system regulation (21 CFR Part 820). Design verification and validation tests were conducted to ensure that the modifications did not affect the essential performance of the device and the device functions as intended.

The following tests were conducted for the modified device:

1. **System Verification and Software Validation**
   - Functional Verification and Software Validation
     - Software Verification (Functional Tests)
     - Regression
     - Safety Systems Verification
     - Simulated Dialysis Treatment
     - Production Test Procedure
     - Unstructured and Static Code Verification
   - System Performance

2. **System Safety**
   - Electromagnetic Compatibility
3. **Usability (Formative and Summative)**

I. Conclusion

Test results demonstrated that the modified 2008T Hemodialysis Machine with optional CLiC functions as intended and met pre-determined acceptance criteria. Results of system/software verification/validation testing, safety testing, and summative usability testing do not raise any new concerns with regard to safety or effectiveness.

FMC-RTG concludes that, within the meaning of the Medical Device Amendments Act of 1976, the 2008T Hemodialysis Machine with optional CLiC is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 11, 2013

Fresenius Medical Care Renal Therapies Group, LLC
% Denise Oppermann
Senior Director, Regulatory Affairs – Device
920 Winter Street
Waltham, MA 02451

Re: K131908
Trade/Device Name: 2008T Hemodialysis Machine
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: July 17, 2013
Received: July 19, 2013

Dear Denise Oppermann,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K131908
Device Name: 2008T Hemodialysis Machine

Indications for Use:

2008T Hemodialysis Machine:
The 2008T Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

bibag System (Optional):
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Crit-Line Clip Monitor (CLiC) (Optional):
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☒ Prescription Use (Per 21 CFR 801 Subpart D)

AND/OR

☐ Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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